

WHAT IS CLAIMED IS:

1. A composition comprising a niosome, wherein the niosome retaining within its structure:

(1) a cyclodextrin inclusion complex formed by a cyclodextrin compound and a steroidal active agent; and

(2) a vesicle formed by a nonionic surfactant;

wherein said niosome can facilitate the transdermal delivery of said steroidal active agent.

2. The composition of claim 1, wherein said steroidal active agent is selected from the group consisting of progestogens, corticosteroids, estrogens, and androgens.

3. The composition of claim 1, wherein said cyclodextrin compound is selected from the group consisting of α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, methyl-cyclodextrin, propyl-cyclodextrin, isopropyl-cyclodextrin, hydroxy-cyclodextrin, hydroxyethyl-cyclodextrin, hydroxypropyl-cyclodextrin, and sulfoalkyl-cyclodextrin.

4. The composition of claim 3, wherein said cyclodextrin compound is β -cyclodextrin.

5. The composition of claim 1, wherein said cyclodextrin inclusion complex is comprised of a cyclodextrin compound and a steroidal active agent in a molar ratio of about 1.0 to 10.0.

6. The composition of claim 1, wherein said nonionic surfactant is selected from the group consisting of alcohols, polyalkylene oxide derivatives, alkyl polyglycosides, derivatives of N-alkyl glucamine; fatty acid esters of
5 sucrose; fatty acid esters of polyethylene glycol; (C₆-C₂₄)alkyl polyglycosides; derivatives of N-(C₆-C₂₄)alkyl glucamine; amine oxides; sorbitol monostearate type surfactant and polyoxyalkylene sorbitan monostearate type surfactant.

7. The composition of claim 6, wherein said nonionic surfactant is a
10 sorbitol monostearate type surfactant.

8. The composition of claim 1, wherein said niosome is comprised of a nonionic surfactant vesicle and a cyclodextrin inclusion complex in a ratio of 1.0 to 25.0.

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9. A method of producing a composition comprising a niosome, wherein the niosome retaining within its structure:

(1) a cyclodextrin inclusion complex formed by a cyclodextrin compound and a steroidal active agent; and

20 (2) a vesicle formed by a nonionic surfactant;

wherein said niosome can facilitate the transdermal and/or transmucosal delivery of said steroidal active agent,

the method comprising the steps of:

(a) forming a cyclodextrin inclusion complex of a steroidal active agent;

25 (b) forming a vesicle solution of a nonionic surfactant;

(c) mixing the vesicle solution of step (b) with the cyclodextrin inclusion complex of step (a) in a molar ratio of about 1.0 to 25.0; and
(d) drying the resulted mixture of step (c).

5 10. The method of claim 9, wherein said steroidal active agent is selected from the group consisting of progestogens, corticosteroids, estrogens, and androgens.

10 11. The method of claim 9, wherein said cyclodextrin compound is selected from the group consisting of α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, methyl-cyclodextrin, propyl-cyclodextrin, isopropyl-cyclodextrin, hydroxy-cyclodextrin, hydroxyethyl-cyclodextrin, hydroxypropyl-cyclodextrin, and sulfoalkyl-cyclodextrin.

15 12. The method of claim 11, wherein said cyclodextrin compound is β -cyclodextrin.

20 13. The composition of claim 9, wherein said cyclodextrin inclusion complex is comprised of a cyclodextrin compound and a steroidal active agent in a molar ratio of about 1.0 to 10.0.

25 14. The method of claim 9, wherein said nonionic surfactant is selected from the group consisting of alcohols, polyalkylene oxide derivatives, alkyl polyglycosides, derivatives of N-alkyl glucamine; fatty acid esters of sucrose; fatty acid esters of polyethylene glycol; (C₆-C₂₄)alkyl polyglycosides; derivatives

of N-(C₆-C₂₄)alkyl glucamine; amine oxides; sorbitol monostearate type surfactant and polyoxyalkylene sorbitan monostearate type surfactant.

15. The method of claim 14, wherein said nonionic surfactant is a sorbitol
5 monostearate type surfactant.

16. The method of claim 9, wherein said mixing of step (a) is a physical mixing process or a freeze-drying process.

10 17. The method of claim 16, wherein the physical mixing process characterized in grinding a mixture of a cyclodextrin compound and a steroidal active agent in a grinder until the mixture is homogenous.

18. The method of claim 16, wherein the freeze-drying process
15 characterized in having the steps of:

- (a) mixing an aqueous solution of a cyclodextrin compound and an alcoholic solution of a steroidal active agent;
- (b) evaporating the solvent of said solution mixture of step (a); and
- (c) freeze-drying the resulted mixture of step (b).

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19. A method for facilitating transdermal delivery of a steroidal active agent, comprising administering to a human or an animal the composition of claim 1.